2018 Current Fiscal Year Report: Secretary's Advisory Committee on Human Research Protections

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Secretary's Advisory Committee on Human Research Protections	9492

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	10/01/2016	10/01/2018	09/30/2020

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	No	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
42 USC 217a, Section 222 of the PHS Act	10/17/1962	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 3 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 3

Meetings and Dates

Purpose	Start	End
The first of three meetings scheduled for FY2018. Topics discussed: HIPAA and Exemption §104(d)(4)(iii), “Context” in Single IRB Review, Expedited Review List, §__.110, Recent FDA Experience with Review under 21 CFR 50.54, and Changes to NIH Certificates of Confidentiality.	10/17/2017	10/18/2017
The 2nd of three meetings scheduled for FY2018. Topics discussed: Overview of Secondary Use of Biospecimens and Data, FAQS on Broad Consent, FAQS on Biospecimens, Repositories, and the Use of Consent under the Current and Revised Common Rule, Single IRB Review, Impact of the European Union’s General Data Protection Regulation on HHS Human Subjects Research, The Role of Key Information in the Revised Common Rule, Patient Representatives’ Perspectives on “Key Information” in Informed Consent:	03/13/2018	03/14/2018

The 3rd of three scheduled yearly meetings in FY2018. Topics discussed: “Key Information” in Informed Consent: Interpretation and Application of Section 116 (a)(5), When is a Parent or Guardian “Reasonably Available” for Purposes of 46.408(b), Update from Division of Education Development OHRP, Payment for Subject Participation, Office of Inspector General Report, July 7, 2017: “OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence”, Discussion of Possible Modification to SACHRP Recommendation for Revised Expedited Review List,	07/10/2018 - 07/11/2018

Number of Committee Meetings Listed: 3

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$35,000.00	$35,000.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$134,000.00	$145,000.00
18a(4). Personnel Pmts to Non-Member Consultants	$15,000.00	$5,000.00
18b(1). Travel and Per Diem to Non-Federal Members	$45,000.00	$35,000.00
18b(2). Travel and Per Diem to Federal Members	$0.00	$0.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$30,000.00	$30,000.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$56,000.00	$50,000.00
18d. Total	$315,000.00	$300,000.00
19. Federal Staff Support Years (FTE)	1.00	1.00

20a. How does the Committee accomplish its purpose?

The Committee is composed of members with varied expertise who provide advice on the development and management of guidance and communications between HHS and its operating and staff divisions and other pertinent elements of the federal government; the biomedical academic, and research communities; non-governmental entities; and other organizations as necessary to further the interests of the human subjects protection enterprise. In addition, the Committee provides counsel on opportunities to improve public awareness of the function and importance of human subjects protection activities.

20b. How does the Committee balance its membership?

The Secretary's Advisory Committee on Human Research Protections (SACHRP) is authorized to have 11 voting members, including the Chair. The voting members are selected from multi-disciplinary backgrounds that are pertinent to human subjects protection and/or clinical research, including law, medicine, genetics, consumer advocacy, IRB administration, research, bioethics and the social sciences. Representatives from the following seven HHS organizational components serve on the Committee as non-voting ex-officio members: Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), National Institutes of Health (NIH), and Office of Civil Rights (OCR).

20c. How frequent and relevant are the Committee Meetings?

The Committee meets three times per year for the purpose of providing advice on the development and management of human subjects research protections, and to further the interests of the human subjects protection enterprise. The Committee hears expert presentations from government agencies, professional organizations, advocacy groups, pharmaceutical companies, and academic research bodies, and responds to HHS' requests for discussion and comment on specific issues. Meetings are tailored to focus on time-sensitive topics, enabling SACHRP to provide recommendations quickly to the Secretary on sensitive issues.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Committee addresses the overall human research subjects protection system, in addition to focusing on specific regulatory issues such as provisions of the Revised Common Rule. The Committee provides advice on the development and management of guidance and communications between HHS and its operating and staff divisions and other pertinent elements of the federal government; the biomedical, academic, and research communities; non-governmental entities; and other organizations as necessary to further the interest of the human subjects protection enterprise. No other Federal Advisory Committee provides this advice.

20e. Why is it necessary to close and/or partially closed committee meetings?

N/A; all Committee meetings are open to the public.

21. Remarks

SACHRP met three times in FY 2018. Please note: costs for this fiscal year reflect actual costs to the extent possible. Funds must be budgeted for payment of members, though members may ultimately not bill for their time. The "Other" column as projected for the future fiscal year necessarily includes costs of minutes and AV. Previously this figure had also included costs for rental of meeting space in the event that HHS space was not available. However, due to the increased effort to enforce the policy that government-sponsored meetings be held in space occupied by the government, it is no longer necessary to factor in this additional cost. Other than ensuring that the SACHRP report posted in the FACA database is accurate and complete, there is no annual reporting requirement to which the Committee must comply. Jonathan Green resigned his term in order to accept a position with NIH. Aviva Katz died prior to fulfilling her term. James Giordano resigned his term early. Taunton Paine replaced Valerie Gordon as the ex-officio member for NIH. The term for all non-HHS ex-officio members ended on 9.30.18.

Designated Federal Officer

Julia G. Gorey Executive Director, SACHRP, Office for Human Research Protections

Committee Members	Start	End	Occupation	Member Designation
Andrews, Anne	10/01/2016	09/30/2018	National Institute of Standards and Technology	Ex Officio Member
Berry, Sandra	12/19/2016	12/18/2019	Senior Behavioral Scientist; Chair, IRB, RAND Corporation	Special Government Employee (SGE) Member
Brooks, Leola	10/01/2016	09/30/2018	Social Security Administration	Ex Officio Member
Bruce, Stephanie	10/01/2016	09/30/2018	Department of Defense	Ex Officio Member
Chesley, Francis	10/01/2016	09/30/2020	Agency for Healthcare Researcgh and Quality	Ex Officio Member
Chingos, Diana	10/29/2014	10/29/2018	Noreen Fraser Foundation	Special Government Employee (SGE) Member
Claypool, Lee	10/01/2016	09/30/2018	US Agency for International Development	Ex Officio Member
Fernandez-Lynch, Holly	10/29/2014	10/29/2018	Harvard Law School	Special Government Employee (SGE) Member
Finley, John	10/01/2016	09/30/2018	US Department of Agriculture	Ex Officio Member
Gaynor, Suzanne	10/01/2016	09/30/2018	Department of Housing and Urban Development	Ex Officio Member
Giordano, James	12/19/2016	12/14/2017	Professor of Biology and Biochemistry; Chief, Neuroethics Studies Program, Georgetown University Medical Center	Special Government Employee (SGE) Member
Goldstein, Russell	10/01/2016	09/30/2018	Central Intelligence Agency	Ex Officio Member
Gordon-Nguyen, Marissa	10/01/2016	09/30/2020	Office of Civil Rights	Ex Officio Member
Gordon, Valerie	10/01/2016	10/01/2017	National Institutes of Health	Ex Officio Member
Green, Jonathan	10/21/2015	09/15/2018	Professor of Medicine, Pathology and Immunology, Washington University School of Medicine	Special Government Employee (SGE) Member
Jeans, Karen	10/01/2016	09/30/2018	Department of Veterans Affairs	Ex Officio Member
Katz, Aviva	12/19/2016	01/17/2018	Associate Professor of Surgery, University of Pittsburgh School of Medicine	Special Government Employee (SGE) Member
King, Nancy	10/15/2015	10/19/2019	Professorof Social Sciences & Health Policy, WAke Forest School of Medicine	Special Government Employee (SGE) Member
Less, Joanne	10/01/2016	09/30/2020	Food and Drug Administartion	Ex Officio Member
Lohrenz, Maura	10/01/2016	09/30/2018	Department of Transportation	Ex Officio Member
Mantz, Jeffrey	10/01/2016	09/30/2018	National Science Foundation	Ex Officio Member
Nelson, Daniel	10/01/2016	09/30/2018	Environmental Protection Agency	Ex Officio Member
O'Donnell, Christopher	10/01/2016	09/30/2018	Department of Homeland Security	Ex Officio Member
Paine, Taunton	10/01/2017	09/30/2020	National Institutes of Health	Ex Officio Member
Pyeritz, Reed	10/29/2014	10/29/2018	University of Pennsylvania	Special Government Employee (SGE) Member
Roberson, LaShondra	10/01/2016	09/30/2020	Center for Disease Control and Prevention	Ex Officio Member
Rodamar, Jeffrey	10/01/2016	09/30/2018	Department of Education	Ex Officio Member
Rosenfeld, Stephen	07/10/2013	07/09/2020	Board Chair, Quorum Review, IRB	Special Government Employee (SGE) Member
Schneider, Victor	10/01/2016	09/30/2018	National Aeronautics and Space Administration	Ex Officio Member
Thaler, Alice	10/01/2016	09/30/2018	Consumer Product Safety Commission	Ex Officio Member

Tracy, Rachel	10/01/2016	09/30/2020	Indian Health Service	Ex Officio Member
Watson, Cheryl	10/01/2016	09/30/2018	Department of Defense	Ex Officio Member
White, Libby	10/01/2016	09/30/2018	Department of Energy	Ex Officio Member
Wolf, Leslie	12/19/2016	12/18/2020	Director of the Center for Law, Health & Society, Georgia State University	Special Government Employee (SGE) Member
Wright-Solomon, Lisa	10/01/2016	09/30/2018	Health Resources and Services Administration	Ex Officio Member

Number of Committee Members Listed: 35

Narrative Description

SACHRP supports HHS by providing recommendations, interpretations and conclusions on issues associated with HHS regulations for the protection of human subjects.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	
Effective grant making	
Improved service delivery	
Increased customer satisfaction	
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	✓
Unable to Determine	
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments
NA

What is the approximate Number of recommendations produced by this committee for the life of the committee?
496

Number of Recommendations Comments
Recommendations are provided to the Secretary of HHS in a series of letters from SACHRP to the Secretary through the Assistant Secretary for Health. These letters outline the committee's interpretation and conclusions on issues associated with HHS regulations for the protection of human subjects, including but not limited to the following: multiple provisions of the newly revised Common Rule, including the requirements for single IRB review, broad consent, the use of the expedited review list, informed consent for the use of biospecimens and data, and the HIPAA exemption; as well as the European Union's General Data Protection Regulations, and topics pertaining to research with children, prisoners, pregnant women, individuals with impaired decision-making, and areas within subpart A, known as the Common Rule. Note that some topics result in multiple recommendations while others may generate one or two overall considerations.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?
10%

% of Recommendations Fully Implemented Comments
Note that many SACHRP recommendations impact issues not yet resolved within the Department, such as guidance documents pertaining to the revised Common Rule; therefore such recommendations, while meaningful to the Department, cannot be quantified as fully or partially implemented at this time. Among the fully implemented recommendations have been recommendations pertaining to: IRB acountability, the formation of a subcommittee to examine harmonization of Federal regulations and guidance affecting human subjejcts research; the addition of ex-officio representation from the Office of Civil Rights; the 45 CFR 46.407 review process for research involving children as subjects; the accreditation of human research protection programs; the interpretation of 45 CFR subpart C (protections for prisoners involved as subjects in human subjects research); a recommendation that a workshop be convened focusing issues pertaining to central IRB review; various FAQs on parental permission, child assent, and documentation of informed consent; IRB accoutability; and continuing review.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

5%

% of Recommendations Partially Implemented Comments

Note that many SACHRP recommendations impact issues not yet resolved within the Department, such as guidance pertaining to the revised Common Rule; therefore such recommendations, while meaningful, cannot be quantified as fully or partially implemented at this time. Among partially implemented recommendations are those pertaining to: 45 CFR 46 subpart D, research involving children as subjects; subpart A continuing review, and expedited review categories; and recommendations calling for initial and continuing training of IRB members, IRB staff, and institutional officials.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

The DFO communicates with the Chair and the full committee at open public meetings. Information about Committee-related matters is also available on the SACHRP website that is managed through the Office for Human Research Protections (OHRP).

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☐
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

The majority of SACHRP's recommendations are under consideration by OHRP, and may result in changes to HHS guidance, regulation, or agency policy. SACHRP recommendations may also be directed towards other components of HHS such as NIH or FDA.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☐
Other	☐

Access Comments

N/A